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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC.,	
Plaintiff,	
v.	10 Civ. 5690 (AKH) ECF Case
UNITED STATES FOOD AND DRUG ADMINISTRATION; KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services; and MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration,	**ANSWER**
Defendants.	

Defendants the United States Food and Drug Administration ("FDA"); Kathleen Sebelius, Secretary of the United States Department of Health and Human Services; and Margaret Hamburg, M.D., Commissioner of Food and Drugs, by their attorney Preet Bharara, United States Attorney for the Southern District of New York, answer the Complaint on information and belief as follows:

1. Defendants deny the allegations set forth in paragraph 1, except admit that triclosan and triclocarban are chemical compounds found in a variety of products, including, but not limited to, certain liquid and bar soaps. Because the second, third, fourth, and sixth sentences of paragraph 1 refer to studies, data, or other research but lack sufficient detail for defendants to identify such studies, data, or other research, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in these sentences. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the fifth sentence of paragraph 1 because it uses vague and undefined terminology, and, in particular, it does not specify how to quantify or otherwise evaluate "substantial human exposure," except admit that antibacterial personal care products are widely used and that humans may be exposed to triclosan and triclocarban.

2. Defendants deny the allegations set forth in the first and second sentences of paragraph 2, except admit that, in 1974, FDA proposed to regulate topical antimicrobial drug products for over-the-counter ("OTC") human use, such as those containing active ingredients, including, but not limited to, triclosan and triclocarban, under a monograph for topical antimicrobial drug products for OTC human use ("monograph for topical antimicrobial drug products"). Defendants further admit that the monograph for topical antimicrobial drug products describes conditions under which topical antimicrobial drugs are generally recognized as safe and effective and not misbranded. Defendants deny the allegations set forth in the third sentence of paragraph 2, except admit that the monograph for topical antimicrobial drug products is currently a tentative final monograph and not a final monograph. Defendants deny the allegations set forth in the fourth and fifth sentences of paragraph 2.

3. Paragraph 3 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response is required, defendants deny the allegations set forth in paragraph 3.

4. Paragraph 4 sets forth plaintiff's characterization of this action to which no response is required. To the extent a response is required, defendants deny the allegations in paragraph 4, except admit that the Natural Resources Defense Council, Inc. ("NRDC") is the plaintiff to this action.

5. Paragraph 5 states plaintiff's legal opinions and conclusions, and a statement as to the purported jurisdiction of this Court, to which no response is required. To the extent that a response is required, defendants deny the allegations set forth in paragraph 5.

6. Paragraph 6 states plaintiff's legal opinions and conclusions, and a statement as to the propriety of venue, to which no response is required.

7. Paragraph 7 states plaintiff's legal opinions and conclusions to which no response is required.

8. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in paragraph 8.

9. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the first three sentences of paragraph 9. Defendants deny the allegations set forth in the fourth and fifth sentences in paragraph 9.

10. Paragraph 10 sets forth plaintiff's prayer for relief, to which no response is required. To the extent a response is required, defendants deny the allegations set forth in paragraph 10.

11. Paragraph 11 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to these allegations is required, defendants respectfully refer the Court to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act"), and its implementing regulations for a complete and accurate statement of their provisions.

12. With respect to the allegations set forth in paragraph 12, defendants admit that Kathleen Sebelius is the Secretary of the United States Department of Health and Human Services (the "Secretary"). The remainder of paragraph 12 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 12 is required, defendants respectfully refer the Court to the Act and its implementing regulations for a complete and accurate statement of their provisions.

13. With respect to the allegations set forth in paragraph 13, defendants admit that Margaret Hamburg, M.D. is the FDA Commissioner of Food and Drugs (the "Commissioner"). The remainder of paragraph 13 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 13 is required, defendants respectfully refer the Court to the Act and its implementing regulations for a complete and accurate statement of their provisions.

14. Paragraph 14 sets forth plaintiff's intention to use a particular term in a particular manner; accordingly, no response is required. To the extent that paragraph 14 can be construed to contain factual allegations to which a response may be deemed to be required, defendants deny all such allegations. Defendants also deny that every instance of plaintiff's use of "the FDA" in the Complaint appropriately applies to all defendants.

15. Paragraph 15 states plaintiff's legal opinion and conclusions to which no response

is required. To the extent that a response to the allegations set forth in paragraph 15 is required, defendants respectfully refer the Court to the Act for a complete and accurate statement of its provisions.

16. Paragraph 16 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 16 is required, defendants respectfully refer the Court to the 1962 amendments to the Act, Pub. L. No. 87-781, 76 Stat. 780 (1962), for a complete and accurate statement of their provisions.

17. Paragraph 17 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 17 is required, defendants respectfully refer the Court to the Act for a complete and accurate statement of its provisions.

18. Paragraph 18 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 18 is required, defendants respectfully refer the Court to the Act for a complete and accurate statement of its provisions.

19. Paragraph 19 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 19 is required, defendants respectfully refer the Court to the Act and its implementing regulations for a complete and accurate statement of their provisions.

20. Paragraph 20 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 20 is required, defendants respectfully refer the Court to the regulations cited in this paragraph for a complete

and accurate statement of their provisions.

21. Paragraph 21 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 21 is required, defendants respectfully refer the Court to the regulations cited in paragraph 21 for a complete and accurate statement of their provisions.

22. Paragraph 22 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 22 is required, defendants respectfully refer the Court to the regulation cited in this paragraph for a complete and accurate statement of its provisions.

23. Paragraph 23 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 23 is required, defendants respectfully refer the Court to the regulation cited in this paragraph for a complete and accurate statement of its provisions.

24. Paragraph 24 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 24 is required, defendants respectfully refer the Court to the regulation cited in this paragraph for a complete and accurate statement of its provisions.

25. Paragraph 25 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations set forth in paragraph 25 is required, defendants respectfully refer the Court to the regulation cited in this paragraph for a complete and accurate statement of its provisions.

26. Paragraph 26 states plaintiff's legal opinion and conclusions to which no response

is required. To the extent that a response to the allegations set forth in paragraph 26 is required, defendants respectfully refer the Court to the regulations cited in this paragraph for a complete and accurate statement of their provisions.

27. Paragraph 27 states plaintiff's legal opinion and conclusions to which no response is required. To the extent that a response to the allegations is required, defendants respectfully refer the Court to the regulation and the pages from the Federal Register cited in paragraph 27 for a complete and accurate statement of their provisions.

27a. To the extent that the underscored heading preceding paragraph 28 can be construed to contain factual allegations, the heading is vague and lacks sufficient detail for defendants to respond. Therefore, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the heading.

28. Because the allegations in paragraph 28 use vague and undefined terminology, and refer to studies, data, or other research relating triclosan or triclocarban that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in paragraph 28.

29. Because the allegations in paragraph 29 refer to "recent and older studies" that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in this paragraph.

30. Because the allegations in paragraph 30 refer to "[n]umerous studies since 2006" that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in this paragraph.

31. Because the allegations in the first sentence of paragraph 31 refer to "[s]everal

animal studies" that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence. Defendants admit the allegations in the second and third sentences of paragraph 31.

32. Defendants admit the allegations in the first sentence of paragraph 32. Because the second and third sentences of paragraph 32 refer to"[*i*]*n vitro* (cell-based) studies" and "[a]nimal studies" that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the second and third sentences in this paragraph.

33. Because the allegations in the first through fourth sentences of paragraph 33 refer to "[r]ecent studies," "*in vitro* and *in vivo* (whole animal) studies," "cell-based studies," and "[a] 2008 study," that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first through fourth sentences in this paragraph. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the fifth sentence of paragraph 33.

34. Because the allegations in paragraph 34 refer to "recent studies" and "older studies" that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in this paragraph.

35. Defendants deny the allegations set forth in paragraph 35, except deny knowledge or information regarding what "other data indicated" because plaintiff did not identify the "other data," admit that, prior to September 13, 1974, FDA appointed an advisory review panel ("Panel") to prepare a report on the safety, effectiveness, and labeling of OTC drug products containing antimicrobial ingredients for topical human use, and that FDA published the

conclusions and recommendations of the Panel in an advanced notice of proposed rulemaking on September 13, 1974, 39 Fed. Reg. 33103 ("1974 ANPRM"), and respectfully refer the Court to the 1974 ANPRM for a complete and accurate statement of its contents.

36. Defendants respectfully refer the Court to the 1974 ANPRM for a complete and accurate statement of its contents, and, to the extent that the allegations set forth in paragraph 36 differ from the contents of the 1974 ANPRM, defendants deny the allegations.

37. Defendants respectfully refer the Court to the 1974 ANPRM for a complete and accurate statement of its contents, and, to the extent that the allegations set forth in paragraph 37 differ from the contents of the 1974 ANPRM, defendants deny the allegations. Defendants further admit that methemoglobinemia is a disorder characterized by the presence of methemoglobin in the blood, and that chloroanilines can induce methemoglobinemia when present at high levels.

38. Because the allegations in the first through fourth sentences of paragraph 38 refer to "[n]umerous studies" and other purported studies, data, or research that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first through fourth sentences in this paragraph. Defendants deny the allegations in the fifth sentence of paragraph 38, except respectfully refer the Court to the 1974 ANPRM for a complete and accurate statement of its contents.

39. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in the first sentence of paragraph 39 because plaintiff uses vague and undefined terminology, except defendants admit that FDA has stated its belief, as of February 2010, that the majority of consumer antibacterial soaps contain triclosan or

triclocarban as active ingredients. Because the second sentence of paragraph 39 refers to studies that plaintiff has not identified, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in this sentence.

39a. To the extent that the underscored heading preceding paragraph 40 can be construed to contain factual allegations, defendants deny the allegations, except admit that the monograph for topical antimicrobial drug products is currently a tentative final monograph and not a final monograph.

40. As to the allegations set forth in paragraph 40, defendants admit that, on January 5, 1972, 37 Fed. Reg. 85 (Jan. 5, 1972), FDA proposed that independent advisory review panels review the safety, effectiveness, and labeling of OTC drugs, and otherwise respectfully refer the Court to the Federal Register document referred to in paragraph 40 for a complete and accurate statement of its contents.

41. Defendants admit the allegations set forth in paragraph 41.

42. Defendants admit the allegations set forth in paragraph 42, except aver that, prior to September 13, 1974, FDA appointed the Panel to review data and information submitted and to prepare a report on the safety, effectiveness, and labeling of OTC drug products containing antimicrobial ingredients for topical human use, including soaps, surgical scrubs, skin washes, skin cleansers, and first-aid preparations.

43. Defendants admit the allegations set forth in the first and second sentences of paragraph 43. With respect to the allegations set forth in the third, fourth, and fifth sentences of paragraph 43, defendants respectfully refer the Court to the 1974 ANPRM for a complete and accurate statement of its contents, and, to the extent that the allegations differ from the contents

of the 1974 ANPRM, defendants deny the allegations.

44. Defendants respectfully refer the Court to the 1974 ANPRM for a complete and accurate statement of its contents, and, to the extent that the allegations set forth in paragraph 44 differ from the contents of the 1974 ANPRM, defendants deny the allegations.

45. Defendants deny the allegations set forth in the first sentence of paragraph 45, except defendants admit that, on January 6, 1978, 43 Fed. Reg. 1210 (Jan. 6, 1978), FDA issued a tentative final monograph for topical antimicrobial drug products ("1978 Tentative Final Monograph"). With respect to the second through fifth sentences of paragraph 45, defendants respectfully refer the Court to the 1978 Tentative Final Monograph for a complete and accurate statement of its contents, and, to the extent that the allegations set forth in the second through fifth sentences of paragraph 45 differ from the contents of the 1978 Tentative Final Monograph, defendants deny the allegations.

46. Defendants respectfully refer the Court to the 1978 Tentative Final Monograph for a complete and accurate statement of its contents, and, to the extent that the allegations set forth in paragraph 46 differ from the contents of the 1978 Tentative Final Monograph, defendants deny the allegations.

47. Defendants deny the allegations in the first sentence of paragraph 47. As to the allegations set forth in the second sentence of paragraph 47, defendants deny knowledge or sufficient information to evaluate the extent to which products containing various active ingredients may have increased in prevalence over time, and therefore deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in this sentence.

48. As to the first sentence of paragraph 48, defendants admit that, on June 17, 1994, 59 Fed. Reg. 31402 (Jun. 17, 1994), FDA issued a tentative final monograph for health-care antiseptic drug products ("1994 Tentative Final Monograph"). With respect to the second through seventh sentences of paragraph 48, defendants respectfully refer the Court to the 1994 Tentative Final Monograph for a complete and accurate statement of its contents, and, to the extent that the allegations set forth in the second through seventh sentences of paragraph 48 differ from the contents of the 1994 Tentative Final Monograph, defendants deny the allegations.

49. Defendants respectfully refer the Court to the 1994 Tentative Final Monograph for a complete and accurate statement of its contents, and, to the extent that the allegations set forth in paragraph 49 differ from the contents of the 1994 Tentative Final Monograph, defendants deny the allegations.

50. Defendants respectfully refer the Court to the 1994 Tentative Final Monograph for a complete and accurate statement of its contents, and, to the extent that the allegations set forth in paragraph 50 differ from the contents of the 1994 Tentative Final Monograph, defendants deny the allegations.

51. Defendants deny the allegations set forth in the first sentence of paragraph 51. As to the allegations in the second sentence of paragraph 51, defendants deny knowledge or sufficient information to evaluate the extent to which drug products containing these active ingredients may have increased in prevalence over time, and therefore deny the remaining allegations, except respectfully refer the Court to the 1994 Tentative Final Monograph for a complete and accurate statement of its contents.

52. As to the first and second sentences of paragraph 52, defendants admit that, on

May 29, 2003, 68 Fed. Reg. 32003 (May 29, 2003), FDA proposed to reopen the administrative record for the rulemaking for topical antimicrobial drug products until August 27, 2003, to accept comments and data concerning health-care antiseptic drug products. Defendants deny the allegations set forth in the third sentence in paragraph 52.

53. As to the allegations set forth in paragraph 53, defendants admit that, on September 13, 1974, FDA published the 1974 ANPRM; on January 6, 1978, FDA published the 1978 Tentative Final Monograph; and, on June 17, 1994, FDA issued the 1994 Tentative Final Monograph. Defendants further admit that the monograph for topical antimicrobial drug products is currently a tentative final monograph and not a final monograph. Defendants deny, however, that the first sentence in paragraph 53 sets forth a full or complete description of the rulemaking history for the monograph for topical antimicrobial drug products. As to the second sentence in paragraph 53, defendants lack knowledge or sufficient information to evaluate the extent to which drug products containing these active ingredients may have proliferated on the market over time. Therefore, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the remainder of the second sentence of paragraph 53.

54. As to the allegations set forth in paragraph 54, defendants admit that FDA representatives met with NRDC, and others, on July 13, 2009, and that during that meeting FDA was questioned about the status of the monograph for topical antimicrobial drug products. Defendants further admit that FDA did not disclose privileged information regarding its deliberations and plans for finalizing the monograph for topical antimicrobial drug products during that meeting. Defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations set forth in paragraph 54.

55. As to the allegations set forth in paragraph 55, defendants admit that NRDC sent FDA a letter, dated September 30, 2009. The remainder of paragraph 55 includes a quote to which no response is required. To the extent that a response is required, defendants admit that the quoted language in paragraph 55 is contained in the September 30, 2009 letter but deny that such language reflects the full character, contents, or purpose of that letter.

56. Defendants deny the allegations set forth in paragraph 56, except admit that FDA responded to NRDC's September 30, 2009 letter by letter dated May 28, 2010. Defendants further admit that FDA has not provided plaintiff with a detailed timeline for finalizing the monograph for topical antimicrobial drug products.

57. As to the allegations set forth in paragraph 57, defendants admit that Chairman Edward J. Markey sent Commissioner Hamburg a letter dated January 5, 2010, which requested information related to the monograph for topical antiseptic drug products. The remainder of paragraph 57 includes quotes to which no response is required. To the extent that a response is required, defendants admit that the quoted language in paragraph 57 is contained in the January 5, 2010 letter but deny that it reflects the full character, contents, or purpose of that letter.

58. As to the allegations set forth in paragraph 58, defendants admit that FDA responded to Chairman Markey by letter dated February 23, 2010. The remainder of paragraph 58 includes quotes to which no response is required. To the extent that a response is required, defendants admit that the quoted language in paragraph 58 is contained in the February 23, 2010 letter but deny that it reflects the full character, contents, or purpose of that letter.

59. The first and third sentences of paragraph 59 refer to FDA's February 23, 2010 response to Chairman Markey and include quotes to which no response is required. To the extent

that a response is required, defendants admit that the quoted language in paragraph 59 is contained in the February 23, 2010 letter but deny that it reflects the full character, contents, or purpose of that letter. As to the second sentence in paragraph 59, defendants admit that, in the February 23, 2010 letter, FDA acknowledged a lack of sufficient studies and/or data on the reproductive/developmental toxicity and endocrine disruption potential for triclosan.

60. As to the first sentence of paragraph 60, defendants admit that, on April 8, 2010, FDA posted on its website an article entitled, "Triclosan, What Consumers Should Know." The remainder of the first sentence of paragraph 60 contains a quote to which no response is required. To the extent that a response is required, defendants admit that the quoted language in paragraph 60 is contained in the April 8, 2010 article but deny that such language reflects the full character, contents, or purpose of that article. As to the second sentence of paragraph 60, defendants admit that FDA announced in the April 8, 2010 article that the agency is working to continue its scientific and regulatory review of triclosan and incorporate the most up-to-date data and information available into the regulations that govern the use of triclosan in consumer products. As to the second sentence of paragraph 60, defendants further admit that the April 8, 2010 article stated FDA's intention to communicate the findings from the agency's review to the public in spring 2011.

60a. To the extent that the underscored heading preceding paragraph 61 can be construed to contain factual allegations, defendants deny the allegations and aver that the monograph for topical antimicrobial drug products is currently a tentative final monograph and not a final monograph.

61. Defendants deny.

62. Defendants deny.

63. The first sentence in paragraph 63 purports to describe the 1978 Tentative Final Monograph to which no response is required. To the extent that a response is required, defendants admit that the quoted language in paragraph 63 is contained in the 1978 Tentative Final Monograph and respectfully refers the Court to that document for a true and complete statement of its contents. As to the second sentence in paragraph 63, because defendants do not have present-day or historical data reflecting or comparing consumer use of antimicrobial drug products, defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained therein, and therefore, deny the allegations in the second sentence.

64. Paragraph 64 refers to FDA's February 23, 2010 response to Chairman Markey and includes quotes to which no response is required. To the extent that a response is required, defendants admit that the quoted language in paragraph 64 is contained in the February 23, 2010 letter but deny that these quotes reflect the full character, contents, or purpose of that letter.

65. The first and second sentences of paragraph 65 refer to FDA's February 23, 2010 response to Chairman Markey and include quotes to which no response is required. To the extent that a response is required, defendants admit that the quoted language in paragraph 65 is contained in the February 23, 2010 letter but deny that these quotes reflect the full character, contents, or purpose of that letter. The third sentence in paragraph 65 purports to describe the 1978 Tentative Final Monograph to which no response is required. To the extent that a response is required, defendants respectfully refer the Court to that document for a complete and accurate statement of its contents.

66. The first sentence in paragraph 66 contains allegations anticipating future events that have not transpired, and defendants deny knowledge or information sufficient to form a belief as to the truth or falsity of such allegations. To the extent that a response is required, defendants deny all allegations in the first sentence of paragraph 66, except admit that there is a need for additional safety and efficacy data for triclosan and triclocarban, among other things, before FDA can finalize the monograph for topical antimicrobial drug products. The second sentence in paragraph 66 includes a quote, to which no response is required. To the extent that a response is required, defendants admit that the quoted language in the second sentence of paragraph 66 is contained in the 1974 ANPRM, but because the quoted language is taken out of context and used to characterize plaintiff's claims in this lawsuit, defendants deny the remaining allegations contained in the second sentence

67. Defendants deny.

68. Defendants reassert and incorporate by reference herein each of their responses to paragraphs 1 through 67 of the Complaint as set forth fully herein.

69. Defendants deny.

70. Defendants deny.

71. The remaining allegations in the Complaint constitute plaintiff's request for relief to which no response is required. To the extent a response is required, defendants deny that plaintiff is entitled to the requested relief or to any relief whatsoever.

72. Defendants deny each and every allegation in the Complaint that has not heretofore been specifically admitted, answered, or otherwise responded to.

FIRST AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction to entertain the plaintiff's Complaint.

SECOND AFFIRMATIVE DEFENSE

The plaintiff lacks standing to pursue the claims articulated in the Complaint.

THIRD AFFIRMATIVE DEFENSE

The allegations in the Complaint fail to state a claim upon which relief may be granted.

FOURTH AFFIRMATIVE DEFENSE

The plaintiff has failed to exhaust available administrative remedies.

FIFTH AFFIRMATIVE DEFENSE

The Court lacks authority to grant the relief requested.

SIXTH AFFIRMATIVE DEFENSE

To the extent plaintiff's claims may be barred by one or more affirmative defenses not specifically cited above, and which cannot be determined at this time, defendants incorporate all such affirmative defenses herein.

WHEREFORE, defendants demand judgment dismissing the Complaint and granting such other and further relief as this Court deems proper, including costs and disbursements.

Dated: New York, New York
September 29, 2010

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